

Whole Food Supplements

August 8, 2001

The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204



Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- 1. The ProtomorphogenTM extracts found in Symplex F support the healthy functioning of the adrenal, thyroid, and pituitary glands, and reproductive organs.
- 2. These glands support the body's hormonal system, cardiovascular and muscle function, central nervous system response to stress, energy production, basal metabolism rate, and protein synthesis.

These statements are made for a dietary supplement containing a proprietary blend of magnesium citrate, bovine ovary PMGTM extract, bovine adrenal PMGTM extract, bovine pituitary PMGTM extract, bovine thyroid PMGTM extract (processed to remove its thyroxine). Other ingredients include calcium lactate, cellulose, and calcium stearate. The name of the product is Symplex® F.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

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